Patent Claims

1. Pharmaceutical composition for oral administration, containing at least one pharmaceutical active ingredient in an effective amount and comprising one or more coated particles which have a core containing the at least one pharmaceutical active ingredient, and have a coating consisting of one or more layers, characterized in that

(a) the coating layer or the coating layers contain at least one hydratable, pharmaceutically acceptable polymer which, on contact with saliva or water, forms a coherent, mouldable, viscous mass which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the mass, and release of active ingredient in the mouth, and

(b) the coating layer or the outermost of the coating layers contains an effective amount of at least one salivation-promoting agent.

2. Composition according to Claim 1, characterized in that it contains as hydratable polymer a nonionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 10,000 mPa·s or an ionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 30,000 mPa·s.

3. Composition according to Claim 1 or 2, characterized in that it contains as hydratable polymer methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, polyvinylpyrrolidone, sodium carboxymethylcellulose, polyacrylic

acid, polyacrylate, alginic acid, alginate, pectin, xanthan, galactomannan, guar gum, hydroxypropyl-guar gum, gelatin and/or gum arabic.

4. Composition according to any of Claims 1 to 3, characterized in that it contains a hydratable polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of at least about 25 mPa·s.

5. Composition according to any of Claims 1 to 4 characterized in that the hydratable polymer has an average particle size not exceeding 200 µm.

6. Composition according to any of Claims 1 to 5, characterized in that the coating is present in an amount of from 5 to 75% by weight, based on the essentially anhydrous composition.

7. Composition according to any of Claims 1 to 6 characterized in that it contains as pharmaceutical active ingredient loperamide, mesalazine, olsalazine, cimetidine, ranitidine, famotidine, nizatidine, omeprazole, sucralfate, pantoprazole, pancreatin, bisacodyl, lactulose, acetylsalicylic acid, paracetamol, ibuprofen, morphine, tramadol, naproxen, diclofenac, piroxicam, terfenadine, astemizole, ambroxol, acetylcysteine, theophylline, atenolol, nifedipine, diltiazem, verapamil, isosorbide mononitrate, amitriptyline, nitrazepam, budesonide, ciprofloxacin, norfloxacin, ofloxacin, amoxicillin, cefaclor, cefadroxil, tetracycline, erythromycin, a pharmaceutically acceptable salt of one of these active ingredients or a combination of two or more of these active ingredients and salts.

8. Composition according to any of Claims 1 to 7, characterized in that it contains as salivation-

promoting agent a water-soluble organic acid or a water-soluble salt of a water-soluble organic acid and/or a water-soluble, osmotically active substance.

9. Composition according to any of Claims 1 to 8, characterized in that it contains as salivation-promoting agent tartaric acid, citric acid, malic acid, ascorbic acid, a sodium or potassium salt of these acids, glucose, fructose, sucrose, xylitol, mannitol, sorbitol, maltitol or a combination of two or more of these compounds.

10. Composition according to any of Claims 1 to 9 characterized in that the coating consists of two or more layers, and the viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of the hydratable polymer in a layer of the coating is in each case no greater than the viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of the hydratable polymer in the adjacent inner layer of the coating.

11. Composition according to Claim 10, characterized in that the outermost layer of the coating contains a hydratable polymer with a viscosity of from 25 to 5000 mPa·s, and the second outermost layer of the coating contains a nonionic hydratable polymer with a viscosity of from 5000 to 10,000 mPa·s and/or an ionic hydratable polymer with a viscosity of from 5000 to 30,000 mPa·s, where the viscosities in each case relate to the viscosity of a 1% strength (weight-weight) aqueous solution of the polymer measured at 25°C.

12. Composition according to Claim 10 or 11, characterized in that the outermost layer of the coating contains polyvinylpyrrolidone or a cellulose ether

with a viscosity of from 25 to 5000 mPa·s, and the second outermost layer of the coating contains sodium carboxymethylcellulose with a viscosity of from 5000 to 8000 mPa·s, polyacrylic acid with a viscosity of from 5000 to 30,000 mPa·s or a cellulose ether with a viscosity of from 5000 to 10,000 mPa·s, where the viscosities in each case relate to the viscosity of a 1% strength (weight/weight) aqueous solution of the polymer measured at 25°C.

13. Composition according to any of Claims 10 to 12, characterized in that a hydratable polymer with an average particle size not exceeding 50 µm is used in the second outermost layer of the coating.

14. Composition according to any of Claims 10 to 13, characterized in that the second outermost layer of the coating is present in an amount of from 0.25 to 50% by weight, calculated as essentially anhydrous layer and based on the essentially anhydrous active ingredient-containing core, and the outermost layer of the coating is present in an amount of from 3 to 60% by weight, calculated as essentially anhydrous layer and based on the essentially anhydrous composition.

15. Composition according to any of Claims 1 to 14, characterized in that the core has a taste-masking coating layer which is resistant to gastric fluid or delays the release of active ingredient.

16. Composition according to any of Claims 1 to 15, characterized in that the coated particles have a maximum diameter of from 0.25 to 12 mm.

17. Composition according to any of Claims 1 to 16, characterized in that it contains several coated particles, and the mouldable mass formed on contact

with saliva causes the particles to stick together.

18. Composition according to any of Claims 1 to 16, characterized in that it consists of a single coated particle which has a maximum diameter of from 3 to 12 mm.

19. Composition according to any of Claims 1 to 18, characterized in that it is essentially anhydrous.

20. Composition according to any of Claims 1 to 17, characterized in that it contains several coated particles and water in an amount of from 23 to 75% by weight, and is in the form of a single, coherent, viscous mass with sufficient consistency to allow it to be taken, without disintegrating, by hand or using a spoon or spatula.

21. Process for producing the pharmaceutical composition defined in Claims 1 to 20, characterized in that one or more particles containing at least one pharmaceutical active ingredient in an effective amount are coated with one or more layers, where

(a) the layer or layers contain at least one hydratable, pharmaceutically acceptable polymer which, on contact with saliva or water, forms a coherent, mouldable, viscous mass which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the mass, and active ingredient being released in the mouth, and

(b) the layer or the outermost layer contains an effective amount of at least one salivation-promoting agent,

in that, if required, the coated particles are converted with pharmaceutical ancillary substances into

a pharmaceutical presentation, and

in that, if required, the composition is mixed with water in an amount of up to about 300% by weight, based on the essentially anhydrous composition.

22. Pharmaceutical composition for oral administration, comprising one or more particles which contain at least one pharmaceutical active ingredient in an effective amount, and a coherent, viscous mass which is formed by contact with saliva, is slippery on the surface and does not adhere to the oral mucosa, which envelops the active ingredient-containing particle or the active ingredient-containing particles, and which prevents active ingredient-containing particles escaping from the mass and active ingredient being released in the mouth, and which contains an effective amount of at least one salivation-promoting agent and at least one hydratable, pharmaceutically acceptable polymer in at least partly hydrated form.

23. Medicinal product pack comprising a pharmaceutical composition according to any of Claims 1 to 20 and the instructions that the composition be taken by direct administration into the mouth or, before intake, be mixed with a metered amount of from 30 to 300% by weight of water, based on the essentially anhydrous pharmaceutical composition.

24. Method for treating or preventing diseases by oral administration of a pharmaceutical composition, comprising the production of the pharmaceutical composition defined in Claims 1 to 20, if required the addition of a metered amount of from 30 to 300% by weight of water, based on the essentially anhydrous composition, and direct administration of the composi-

tion into the mouth.